

from the budget of both payers would raise by 579.5 thousand PLN (130.3 thousand €) in 2009 and 1.2 mln PLN (261 thousand €) in 2010. Depending on parameter changes, the budget would change by $\pm 17\%$ and $\pm 19\%$ for NHS and both payers perspective, respectively. **CONCLUSIONS:** The reimbursement of vildagliptin will cause the raise of NHF expenses by 0.37% in 2009 and 0.70% in 2010 of the budget spent for oral drugs reimbursed in diabetes mellitus. For both payers' perspective, the reimbursement of vildagliptin will cause the raise expenses by 0.27% in 2009 and 0.53% in 2010 of the budget.

COST OF AN EPISODE OF DIABETIC FOOT ULCER IN SPAIN

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OBJECTIVES: To estimate the health care direct costs of an episode of extensive superficial or deep uncomplicated foot ulcer of neuropathic origin in patients with diabetes in Spain and identify the key factors that influence total costs. **METHODS:** A retrospective observational study of patients with an episode of foot ulcer during the period from January 2007 through December 2008 in 10 Spanish centres was performed. Data about sociodemographic characteristics, duration of the episode and health care-related resources were considered. The following resources were collected from hospital records: inpatient hospitalisations, surgeries, outpatient visits (specialists and primary care physician), diagnostic procedures, laboratory tests, ulcer-related cures, antibiotics and orthotic devices. Unitary cost (€, year 2009 values) data were taken from a Spanish Database of Health Costs and the Catalogue of Medicinal Products. **RESULTS:** Ninety-two patients (29.3% with one or more previous ulcers) with a foot ulcer episode were identified. The majority of cases were males (76.9%). Patients' mean age was 65.20 ± 10.90 years and 50.0% of these were retired. Average duration of an ulcer episode was 131 ± 123 days. Most prevalent comorbidities were arterial hypertension (62.0% of cases), diabetic retinopathy (41.3%), renal impairment (30.4%), dyslipidemias (25.0%) and myocardial infarction (19.6%). Concomitant infections during the episode were reported in 33.7% of patients. The average cost per patient and ulcer episode was €17,262 (95% confidence interval [CI], €11,315, €23,715). The most important categories of costs were for surgeries (€7054, 95%CI, €6043–€8200, 40.9% of costs), inpatient hospitalisations (€6197, 95%CI, €3605–€8878, 35.9% of total costs), and ulcer-related cures (€2864, 95%CI, €1127–€4759, 16.6% of total costs). Among surgeries, the most relevant were debridements and amputations. **CONCLUSIONS:** An episode of a neuropathic extensive superficial or deep uncomplicated diabetic foot ulcer generates a substantial economic burden, with a mean cost per patient of €17,262. Surgeries, hospitalisations and ulcer-related cures represent 93.4% of total costs.

GLYCEMIC CONTROL IN THE INPATIENT SETTING: INSULIN ASPART COMPARED TO HUMAN BOLUS INSULIN

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OBJECTIVES: Poor glycemic control is associated with increased morbidity and mortality among hospitalized patients. Insulin aspart may be more effective in achieving glycemic control than human insulin. This study compares glycemic control, length of stay (LOS), hospital mortality, and charges for hospitalized patients receiving insulin aspart or human bolus insulin. **METHODS:** This study is a retrospective analysis of the *Health Facts*® database (Cerner Corporation, Kansas City, MO). *Health Facts* is a unique database built from hospital comprehensive clinical records including pharmacy, laboratory, emergency room, admission, and billing information from hospitals throughout the United States, all time-stamped and sequenced. The sample included 36,991 medical patients with discharge dates from January 1, 2004 through December 31, 2007. Patients were segmented into those who exclusively received insulin aspart ($n = 4605$, 12.5%) or human ($n = 32386$, 87.6%) bolus insulin. Outcomes of interest included blood glucose (BG) control (overall mean BG < 140 mg/dL), length of stay (LOS), in-patient mortality, and hospital charges (in \$2007). Results were compared with t-tests or chi-square tests. **RESULTS:** Insulin aspart patients demonstrated better blood glucose control (34.22% vs. 30.78% with mean BG < 140 mg/dL, $p < 0.001$) even though they experienced increased illness as demonstrated by higher Charlson comorbidity scores (2.0 (1.7) vs. 1.9 (1.8), $p < 0.001$) and had more heart, kidney, and lung diseases diagnosed during their stay. Insulin aspart was also associated with shorter LOS (5.5 (5.4) vs. 6.3 (6.8) $p < 0.001$), lower mortality (3.8% vs. 8.7%, $p < 0.001$) and fewer total charges (\$25,074 (28,775) vs. \$33,472 (41704), $p < 0.001$). **CONCLUSIONS:** Insulin aspart patients appeared to have better glycemic control, shorter LOS, lower mortality and reduced hospital charges than patients on human bolus insulin. Multivariate adjustments are needed to confirm these findings but the unadjusted results suggest insulin aspart is associated with better outcomes than human bolus insulin.

PDB15

TREATMENT COSTS ATTRIBUTABLE TO BEING OVERWEIGHT OR OBESE IN U.S. DIABETIC PATIENTS: QUANTILE REGRESSION APPROACH

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OBJECTIVES: To estimate treatment costs attributable to overweight or obese status in diabetic patients in the U.S.A. **METHODS:** The data was drawn from the 2003–2006 Medical Expenditure Panel Survey. Adult patients (18–74 years-old) with diabetes were identified based on a self-reported diagnosis or ICD-9-CM code of 250. Patients with pregnancy, malignancy, kidney dialysis, immunodeficiency, or body-mass-index (BMI) < 18.5 were excluded. Medical treatment costs included office based physician/outpatient visits, emergency room visits, or hospitalizations, excluding dental problems and injuries. The treatment costs attributable to being overweight ($25 \leq \text{BMI} < 30$) or obese ($\text{BMI} \geq 30$) at various points of the cost distribution were estimated using weighted quantile regression after controlling for demographics, comorbidities, and other study variables. Treatment costs attributable to being overweight/obese were calculated by the differences in the actual treatment costs for overweight/obese patients and the expected costs if obese patients were normal-weight patients using the study variable coefficients obtained from all patients. All costs were converted to 2006 U.S. dollars using price indices. Data were analyzed using SAS and SUDAAN. **RESULTS:** A total of 5338 patients with diabetes were selected for this study. Approximately 88% of the diabetic patients were overweight (31%) or obese (57%). Compared with normal-weight patients, the incremental treatment costs attributable to obesity were significantly higher by \$35, \$96, \$196, \$290, and \$739 at the 10th, 25th, 50th, 75th, and 90th percentiles, respectively. Similar trends were found in overweight patients compared with those of normal-weight, but the attributable costs were not significantly different except at the 75th percentile point. **CONCLUSIONS:** The overall economic burdens attributable to being overweight and obese in diabetic patients were substantial and increased significantly in the upper tail of the treatment cost distribution. The important finding that the magnitude of attributable costs increased across the distribution of treatment costs would not have been possible without the quantile regression method.

PDB18

COST OFFSETS ASSOCIATED WITH USE OF EXENATIDE COMPARED TO GLARGINE FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The clinical effectiveness of exenatide and glargine is well established for the treatment of type 2 diabetes (T2D). However, the relative economic and utilization impact of these therapies is uncertain. This study examined the cost offsets associated with the use of exenatide compared to glargine in patients with T2D. **METHODS:** A retrospective analysis was conducted using a large, managed care claims database. Adult patients with T2D who had initiated either exenatide ($N = 9264$) or glargine ($N = 3791$) therapy between April 1, 2005 and June 30, 2007 with pre- (6 months) and post-index (12 months) continuous eligibility were included. Annual mean total medical costs and several mean cost components were estimated using propensity score stratification to control for baseline demographic, clinical and resource utilization variables. Mean costs were estimated using nonparametric bootstrapping. **RESULTS:** Exenatide-treated patients had significantly lower total direct medical (\$20,792 vs. \$24,954, $p < 0.0001$), inpatient (\$4,836 vs. \$6,966, $p < 0.0001$), outpatient (\$9,510 vs. \$11,858, $p < 0.0001$), and emergency room (ER) costs (\$96 vs. \$131, $p = 0.04$). Exenatide-treated patients had higher total prescription costs (\$6349 vs. \$6000, $p = 0.0004$). Furthermore, exenatide-treated patients had significantly lower costs of hospitalization (\$4802 vs. \$6873, $p < .0001$) mainly due to lower macrovascular complications (\$1620 vs. \$2661, $p = 0.001$), and also lower office visit costs (\$3317 vs. \$4176, $p < 0.0001$) and hospital outpatient visits (\$5144 vs. \$6608, $p < 0.0001$) compared to glargine-treated patients. Although prescription costs of exenatide was higher than glargine (\$1544 vs. \$843, $p < 0.0001$), exenatide-treated patients incurred significantly lower costs of concomitant antidiabetic medications (\$1283 vs. \$1415, $p < 0.0001$) and other prescription medications (\$3235 vs. \$3438, $p = 0.015$) compared to glargine-treated patients. **CONCLUSIONS:** Patients who initiated exenatide treatment had significantly lower total medical costs mainly due to lower inpatient, outpatient and ER visits despite having higher total prescription costs. Although, the index-drug costs were higher for exenatide, cost savings were observed in hospitalizations, office visits, and hospital outpatient visits.

PDB19

TIME TO OPIOID USE AND HEALTH CARE COSTS AMONG PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHIC PAIN WHO INITIATED DULOXETINE VERSUS OTHER TREATMENTS

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OBJECTIVES: To compare the use of opioids and health care costs between patients with diabetic peripheral neuropathic pain (DPNP) who initiated treatment with duloxetine versus other standard of care DPNP treatments. **METHODS:** This retrospective cohort study analyzed administrative claims database 2004–2006 from a large US commercially-insured population to assess opioid utilization and health care costs over

a one-year follow-up period. DPNP patients aged 18–64 years initiated on duloxetine (Dulox) or other standard of care (SOC) therapies, including tricyclic, venlafaxine, gabapentin, and pregabalin, between March 1, 2005 and December 31, 2005 were selected. Initiation of treatment was defined as no pill coverage over the prior 90 days. The first observed prescription claim denoted as the “index date”. SOC patients were randomly matched (ratio 1:1) to Dulox patients via propensity score matching controlling for patient demographics, clinical characteristics, and prior health care utilization. Opioid utilization and health care costs were compared between matched study cohorts. **RESULTS:** Propensity score matching resulted in 112 Dulox and 112 SOC patients. Compared with SOC patients, Dulox patients were less likely to use any DPNP-related opioids (52.7% vs. 82.1%, $p < 0.01$). Patients who initiated duloxetine had 2.0 fewer opioids prescription dispensed ($p < 0.01$) and 32 fewer days on opioids ($p < 0.01$) than those in the SOC cohort. Patients in the Dulox cohort were initiated on opioids approximately four months later than SOC patients ($p < 0.01$). The cumulative opioid dose in morphine equivalents were significantly lower for Dulox patients than SOC patients (833 mg vs. 3,114 mg, $p < 0.01$). Dulox cohort had significantly lower total health care costs than SOC cohort (\$22,273 vs. \$34,785, $p < 0.05$), primarily due to lower outpatient costs (\$7,567 vs. \$17,584, $p < 0.01$). **CONCLUSIONS:** Duloxetine treatment appears to be associated with delayed use of opioids among patients with DPNP. Health care costs were also lower for patients initiated on duloxetine vs. SOC treatment.

PDB20

A COST CONSEQUENCE MODEL TO ASSESS THE ECONOMIC IMPACT IN GERMANY OF PATIENTS ACHIEVING KDOQI™ TARGETS WITH THE USE OF A COMBINATION OF CINACALCET + TRADITIONAL THERAPY (TT) COMPARED WITH TT ALONE

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OBJECTIVES: From a German health care perspective, to evaluate the cost per patient in achieving KDOQI™ targets with the use of a combination of cinacalcet + traditional therapy (TT). **METHODS:** The number of patients eligible for cinacalcet was derived from the OPen-label, Randomized Study Using Cinacalcet HCL To IMprove Achievement of KDOQI™ Targets in Patients With End-Stage Renal Disease (OPTIMA) Trial [1], assessing the efficacy of adding cinacalcet to a TT protocol in controlling bone metabolic parameters in dialysis patients with secondary hyperparathyroidism over a 23-week period. KDOQI™ targets considered are: iPTH ≤ 300 pg/mL, calcium (Ca) < 9.5 mg/dL and phosphorus (P) < 5.5 mg/dL. Resource utilization included the average dose per day, average duration of therapy, and cost per dose. The model compares the cost per patient who achieves target and the cost per week to maintain target, with the use of a combination of cinacalcet + TT relative to TT alone or no therapy. **RESULTS:** At the end of the study period, 30.2% (111) of patients receiving cinacalcet + TT achieved their KDOQI™ targets, compared with 2.7% (5) for TT. The average cost per week of maintaining target was €349.10 for patients on cinacalcet + TT and €597.29 for patients on TT. The incremental cost per incremental week in target was €491.40 with TT compared with no therapy and was cost-saving (minus 39.68€ per week) with cinacalcet + TT. The incremental cost per incremental patient at target after 23 weeks was €5,895.06 for patients receiving cinacalcet + TT compared with TT and €36,991.66 for patients receiving TT compared with no therapy. **CONCLUSIONS:** Patients administered cinacalcet + TT maintain, on average, KDOQI™ targets longer than patients receiving TT and require less resources. This translates into lower costs per patient (compared with TT) to achieve and maintain KDOQI™ targets. 1. Messa et al. Clin J Am Soc Nephrol. 2008;3:36–45.

PDB21

WHO ARE THEY FOOLING?: COST OF DISEASE OR COMPLICATIONS CAN SIGNIFICANTLY BIAS ESTIMATES UNLESS CONTROL (NON-DISEASED) COSTS ARE NOT ALSO ACCOUNTED FOR IN THE ANALYSIS

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OBJECTIVES: Costing studies often do not identify the excess costs incurred by the health care system for patients with a disease vs. patients without the disease. Using cohort based cost estimates without controlling for costs also incurred by a non-disease population can bias projections, long-term modeling and economic evaluation analyses. The objective of this study was to estimate the prevalence, total and excess costs attributable to diabetes and its complications in Ontario, Canada over 11 years (1995 to 2005). **METHODS:** Newly diagnosed type 1 and 2 diabetes cases aged 35 and over were identified from the Ontario Diabetes Database and matched 1:2 using propensity scores with controls (non-diabetes cases). The following complications were identified: myocardial infarction, stroke, angina, heart failure, blindness in 1 eye, amputation, nephropathy and cataracts. Excess costs of diabetes were estimated as the difference between costs attributed to patients with diabetes vs. those attributed to patients without diabetes. **RESULTS:** The prevalence of diabetes rose drastically, from 6.5 to 10.5%. Excess costs were \$2930 in the year of diabetes diagnosis and \$1240 in subsequent years. In the year of an event, cost differences were greatest for patients with diabetes who had an amputation (\$5133), followed closely by nephropathy (\$4117) and stroke cases (\$3965). Excess costs were apparent for both females and males, and the cost amount was strongly associated with increasing age. **CONCLUSIONS:** Results demonstrate that relying on costs from a population with only the disease (i.e. diabetes) with no control can overestimate costs of the disease and

associated complications. Assessing excess costs of disease is important for costing studies, longer-term modeling and economic evaluations in general. Existing studies which do not account for excess cost may overestimate cost and potentially bias estimates of cost-effectiveness or cost savings due to effective patient management.

PDB22

SELF-MONITORING OF BLOOD GLUCOSE (SMBG) FOR TYPE 2 DIABETES PATIENTS ON ORAL ANTI-DIABETES DRUGS (OADS): COST-EFFECTIVENESS IN FRANCE, GERMANY, AND SPAIN

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OBJECTIVES: Stakeholders in Europe remain keenly interested in obtaining information to help assess country-specific value of SMBG for patients with type-2 diabetes and treated with OADs. From national reimbursement system perspectives in France, Germany, and Spain, this study modeled the long-term (40-year) cost-effectiveness of SMBG at 1, 2, or 3x/day (vs. no SMBG) for this patient population. **METHODS:** SMBG input costs (strips, lancets, monitors, nurse training) were supplied by LifeScan in €2007 values and applied as appropriate for each country's current reimbursement policy. Cohort characteristics and assumed HbA_{1c} effects came from a U.S. Kaiser Permanente longitudinal analysis of new SMBG users. Country-specific complication costs obtained from published sources were inflated to €2007 values. Base-case outcomes were discounted at 3% per annum for France and Germany; 6% for Spain. Sensitivity analyses varied time horizon (5, 10, 20 years) and discount rates relevant to each country. Sensitivity analyses also included a –0.036 dis-utility for SMBG in year 1. **RESULTS:** Incremental cost-effectiveness ratios (ICERs) were largest in France, where monitors were included as reimbursed SMBG acquisition costs. ICERs for SMBG 1x, 2x, and 3x/day were €12,114, €6,282, and €7,958, respectively. ICERs for SMBG 1 or 2x/day were <€2,000 in Germany and <€4,000 in Spain. ICERs for SMBG 3x/day were <€6000/QALY in both countries. Results were most sensitive to the 5-year time horizon. With the SMBG dis-utility, ICERs increased only modestly (€321–€2264/QALY) in all scenarios except SMBG 1/day in France, where it increased by €9578. **CONCLUSIONS:** With SMBG cost assumptions reflecting current payer reimbursement in France, Germany, and Spain, the use of SMBG was found to be cost-effective. This study adds to the literature on the impact of assuming an SMBG dis-utility, and on the country-specific, long-term value of SMBG as a management tool for type-2 diabetes patients treated with OADs.

PDB23

PREDICTING COST-EFFECTIVENESS OF A DIABETES HEALTH CARE PROGRAM IN BELGIUM AS A POLICY MANAGEMENT TOOL

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OBJECTIVES: Diabetes type 2 is a major health problem with severe complications and a significant impact on quality of life. International guidelines, developed to provide better care and to prevent complications, are difficult to translate into daily practice. Especially the lack of prevention of retinopathy and nephropathy through frequent screening are a current concern. The aim of this study is to assess the minimum impact a program at a pre-specified policy defined cost, supporting general practitioners to put recommendations into daily clinical practice, has to achieve to be cost-effective. **METHODS:** We estimated the minimum number of patients, with a mean age of 65 years, that should be screened annually for respectively retinopathy and nephropathy, for the program at an implementation cost of €195 per patient, to be cost-effective. For both complications, a Markov model, adapted from published peer-reviewed models, was developed simulating the evolution of a patients cohort with type 2 diabetes over 25 years with cycles of 1 year. A public health care payer perspective in a Belgian setting was chosen. Transition probabilities were obtained from local epidemiological studies and published trials. Cost data of the different states were collected from literature and from the National Institute for Health and Disability Insurance. Utility data for all states were obtained from published studies. A ratio of €30,000/QALY was used as threshold of willingness to pay for health gain. **RESULTS:** We found for nephropathy a net-saving cost of €6500/QALY when there is only an increase in annual screening of 10%. For retinopathy we found a net price of €1005 but no health gain. **CONCLUSIONS:** A scientific program in a Belgian setting with a given implementation cost of €195 per patient and a minimum increase in screening in the intervention group, would be cost-effective in the prevention of nephropathy and retinopathy.

PDB24

COST EFFECTIVENESS ANALYSIS OF SWITCHING PATIENTS WITH POORLY CONTROLLED TYPE 2 DIABETES TO BIPHASIC INSULIN ASPART 30 FROM BIPHASIC HUMAN INSULIN 30 IN THE CZECH SETTING

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OBJECTIVES: The aim of this health economic analysis was to assess the cost-effectiveness of biphasic insulin aspart (BIAsp) when switched from biphasic human insulin 30 (BHI), based on type 2 diabetes patients from a prospective, multicentre, open label, non-controlled, observational, 24-week study. **METHODS:** A published and validated computer CORE Diabetes Model was used to project long-term economic and clinical outcomes in sub-cohort of type 2 diabetes patients treated with BIAsp 30 versus BHI 30. The cohort had 831 (372 male) patients. There was HbA_{1c} decrease